HEALTHIER WORKPLACES | A HEALTHIER WORLD

June 10, 2022

Michael S. Regan
Administrator
United States Environmental Protection Agency

AIHA Comments on EPA's Notice of Proposed Rulemaking on the Manufacturing, Processing, Distribution, and Commercial Use of Chrysotile Asbestos

Agency/Docket Numbers: EPA-HQ-OPPT-2021-0057; FRL-8332-02-OCSPP
RIN: 2070-AK86

Dear Administrator Regan:

AIHA, the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety (OEHS), appreciates the opportunity to provide feedback on EPA's notice of proposed rulemaking (NOPR) on the manufacturing, processing, distribution, and commercial use of chrysotile asbestos.

A summary of our responses to the NOPR includes:

1) An alternative to banning materials by following the industrial hygiene hierarchy of controls model. AIHA recognizes that elimination of a hazard is the best control measure; however, the substitution of a less hazardous material is only desirable when a new hazard or risk of catastrophic failure is avoided.

2) EPA's risk assessment for chrysotile asbestos is the basis for the proposal to ban certain asbestos-containing products and for establishing the Existing Chemical Exposure Limit (ECEL). The risk assessment had flaws that were identified by the National Academy of Sciences (NAS) and AIHA which have not been addressed and will likely result in a different overall excess cancer risk determination and ECEL value.

3) An assessment of the technical feasibility for measuring exposures to the proposed ECEL. Several problems exist in measuring exposures at or below the ECEL including: current Phase Contrast Microscopy (PCM) methods cannot differentiate between asbestos and non-asbestos fibers; PCM methods Limit of Detection (LOD) is above

the ECEL; background fiber concentrations can exceed the ECEL; and, environmental conditions contribute to sample overloading or collection efficiency.

Hierarchy of Controls

Introduction

Following the industrial hygiene hierarchy of controls model can help most anyone work safely with most any material in a manner that reduces risks to acceptable levels. There are five components of the hierarchy of controls that flow from most protective to least: elimination, substitution, engineering controls, administrative controls, and personal protective equipment (PPE) and clothing. Each concept has distinct benefits and potential pitfalls, which is why AIHA does not typically support proposed product bans but favors the hierarchy of controls approach.

1. **Eliminate asbestos from the process**
    a. Steps one and two in the hierarchy of controls are really the same. Elimination and substitution both amount to removing asbestos from the process. In "Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act (TSCA)" EPA states that replacements are available for:
        i. Vehicle friction breaks
        ii. Chlor-alkalai plants
        iii. Sheet gaskets

    It would appear that elimination or replacement is viable in all three major areas. We recognize and encourage the use of "replacement risk analysis" to determine the environment, health, and safety downside of any of these changes and an assessment of the relative risks based upon the relevant comparative hazards associated with all materials.

2. **Substitute the asbestos material with an asbestos-free product, if a replacement is needed.**

    The banning of asbestos is not eliminating risks but rather substituting new risks. This means that any alternative methodology should undergo the same level of scrutiny as applied to asbestos so it can be assured that any excess risk is actually lowered rather than introducing new risks that may be as detrimental as those associated with the use of asbestos. Note that membrane cell technology involves per- and polyfluoroalkyl substances (PFAS) chemicals, which have their own health risks.

    Efforts to replace asbestos-containing gasket materials have been an ongoing effort since at least the 1970's in the chemical industry. In many cases, the use of asbestos-containing gaskets has been eliminated. Asbestos-containing gaskets can withstand high temperatures and pressures and are very resistant to the corrosive properties of many chemicals. Before banning asbestos gaskets, EPA should be sure that suitable alternatives exist that can withstand these extreme conditions. A failure of a gasket could easily result in severe injuries or even death to workers near the failure and to offsite communities. For example, asbestos gaskets are used on chlorine tank cars which can be located in communities throughout the country. A chlorine leaking railcar due to a failed gasket could be catastrophic.

3. **Engineer design changes**
    a. Engineering changes tend to be long-range, although they may not be as long-range as the overall process changes described above. The best changes will not require modification of worker behavior and will be relatively maintenance non-intensive.

4. **Administrative controls: Post warning signs and apply labels for asbestos-containing areas and materials**
    a. Control access to areas containing asbestos products
    b. Administrative controls rely heavily on worker behavior, management and supervisory commitment, and the quality of training. United States Occupational Safety and Health Administration (OSHA) specifically prohibits the use of job rotation, which is a main administrative control when seeking to reduce worker exposures.

5. **Personal protective equipment and clothing**
    a. This is the last line of defense and is not recommended unless the more effective controls are in the planning stage or have been shown not to be effective. Issues such as the quality of training, worker compliance, day-to-day and worker-to-worker variation, and the condition of PPE all come into play. This aspect of the hierarchy of controls should be used with caution when working with a high-hazard material such as asbestos.

Risk Evaluation

Risk of inhalation of asbestos

AIHA suggests that EPA's risk evaluation of chrysotile asbestos was not performed properly and was expected to be revised in accordance with the comments on the EPA TSCA process issued by the NAS. AIHA submitted public comments on the scope of Part 2 of the asbestos risk evaluation planned by EPA with the recommendations to address the methodological issues determined by NAS prior to any further activities or regulatory actions on asbestos. The current version of EPA's rulemaking does not respond to the recommendations of various scientific organizations regarding the methodological problems encountered in the previous EPA documents.

In particular, the proposed ECEL for chrysotile asbestos does not have solid toxicological or epidemiological backing. For example, in 2020 Korchevskiy, Rasmuson, Rasmuson, Strode assessed the average total cancer inhalation unit risk for asbestos based on Hodgson, Darnton and Berman, Crump methods as 0.0255 per f/cc for the lifetime exposure.[1] The ECEL proposed by EPA corresponds to the level of risk of 0.16 excess cancer cases per 10,000, significantly lower than the threshold of 1 case per 10,000 proposed by National Institute for Occupational Safety and Health (NIOSH) for workers populations. The level of 0.16 cases per 10,000 can be considered negligible assuming a significant baseline level of lung cancer and mesothelioma in the U.S. population (not less than 100 cases per 10,000 per lifetime).

EPA needs to accurately determine the number of individuals in the chlor-alkali industry at the affected sites that have potential exposure to asbestos. This determination will likely conclude that the total population at all nine sites combined is well less than 100 individuals. Risks expressed in cases per 10,000 have little meaning with very small populations at risk.

Analytical and Exposure Assessment Methods

Several problems exist in measuring exposures at or below the ECEL or action level (AL) including: current PCM methods cannot differentiate between asbestos and non-asbestos fibers; PCM method LOD is above the ECEL; Background fiber concentrations can exceed the ECEL; and environmental conditions contribute to sample overloading or collection efficiency.

The EPA risk assessment model projects excess risk with the continued use of asbestos. All models are based on assumptions. In this case, the assumptions relate to the biological outcomes that can occur and at what level these effects actually do occur. Considering that the risk model is projecting excess risk at exposure levels one to two orders of magnitude below levels that can be measured, the risk projection is an extrapolation of existing information rather than an interpellation. All exposure assessments have limitations. This means that the exposure assessment does not have the ability to quantify exposure below its limitation and therefore cannot be used to delineate effects below the exposure assessment limitations.

These comments relate to the analytical feasibility of an ECEL of 0.005 f/cc as an 8-hr TWA average with an action level of 0.0025 f/cc. The capability of existing analytical methods to measure asbestos was a consideration in establishing the current OSHA (permissible exposure limit) PEL and ACGIH TLV of 0.1 f/cc as an 8-hr TWA with an excursion limit of 1 f/cc over 30-minute period was the analytical limitation of the available analytical method. There are a number of issues associated with the proposed ECEL.

---

[1] Korchevskiy, A., Rasmuson, J., Rasmuson, E., Strode, R., "Inhalation Unit Risk (IUR) of Asbestos Based on Available Science," Inhalation Toxicology, 32:9-10, 372-374, (2020).

First, the PCM cannot differentiate between asbestos and non-asbestos fibers. Non-asbestos fibers include non-asbestos mineral fibers, human-made glass fibers and plant fibers such as those associated with paper products. The method is measuring any fiber >5 µm in length with a length to diameter ratio of at least 3:1. The National Research Council[2] reports (1984) that background levels all fibers of this fiber length and aspect ratio in an outdoor setting not known to contain asbestos sources is 0.008 f/cc - a level 60% greater than the proposed ECEL, and three times the proposed action level. ATSDR (2001) reported ambient outdoor asbestos concentrations in urban areas of the U.S. ranging from 0.000003 to 0.0003 fibers per cubic centimeter (f/cc) (i.e., fiber concentration measured using a phase contrast light optical method). Abelmann et al determined the range of ambient asbestos fiber concentrations between 0.00022 to 0.00093 f/cc.[3] So while it is true that ambient levels of asbestos are below the ECEL and AL, the methods for PCM sampling and analysis can not differentiate between non-asbestos and asbestos fibers from background sources. Therefore, background fibers could indicate that the AL and ECEL are exceeded without the presence of asbestos.

The proposed exposure limits of 0.005 f/cc and 0.0025 f/cc cannot be measured for an 8-hour work shift by existing sampling and analytical protocol for asbestos including OSHA Standard 29 CFR 1910.1001, OSHA Method ID-160, and NIOSH Method 7400 protocols. This is due to the volume of air that would need to be collected to achieve the detection limit necessary to measure the AL and ECEL. The volume of air is a function of flow rate through the sample media, the duration of sample collection, and the loading of the filter and environmental interferences.

The LOD of the PCM method is 0.002 f/cc at the OSHA recommended maximum sampling rate of 2.5 l/minute, 8-hr sample period. The NIOSH 7400 Method has a "quantitative working range is 0.04 to 0.5 fiber/cc for a 1000-L air sample. The LOD depends on sample volume and quantity of interfering dust and is <0.01 fiber/cc for atmospheres free of interferences. From the OSHA Standard 1910.1001 App A, the flowrate of air samples should be between 0.5 lpm and 2.5 lpm for 25 mm cassettes. For statistically reproducible data, the OSHA Method ID-160 and NIOSH Method 7400 recommend fiber density (loading) on samples to range from 100 f/mm^2 to 1300 f/mm^2. Using the maximum flowrate of 2.5 lpm and the minimum fiber density of 100 f/mm^2, the minimum sample time to reach the proposed ECEL of 0.005 f/cc would be 3080 minutes (51 hours and 20 minutes). Using the

[2] Asbestiform Fibers: Nonoccupational Health Risks Committee on Nonoccupational Health Risks of Asbestiform Fibers, Board on Toxicology and Environmental Health Hazards, National Research Council. ISBN: 0-309-55757-7, 334 pages, 8.5 x 11, (1984), This PDF is available from the National Academies Press at: http://www.nap.edu/catalog/509.html

[3] Abelmann A, Glynn ME, Pierce JS, Scott PK, Serrano S, Paustenbach DJ. Historical ambient airborne asbestos concentrations in the United States - an analysis of published and unpublished literature (1960s-2000s). Inhal Toxicol. 2015;27(14):754-66. doi: 10.3109/08958378.2015.1118172. PMID: 26671195.

NIOSH 7400 quantitative working range, the lowest statistically quantifiable limit should be 0.04 f/cc.

Methods of measurement using Transmission Electron Microscopy (TEM) exist including NIOSH 7402 and the German VDI 3492 that is required to reach the German clearance standard of 0.001 f/cc. The benefit of TEM is that the method specifically counts asbestos fibers. These concentrations are typically achieved in a clean environment after an abatement project.

Modifications to OSHA ID160 method now allows up to 5.0 liters per minute and the NIOSH Method 7400 and 7402 allow up to 16 liters per minute. These flow rates may not be achievable on a personal sample but could be achievable on area samples that are near the work. Furthermore, EPA developed techniques such as indirect preparation techniques used on clean-up sites like as Libby, Montana, and others to reduce the amount of interference in heavily loaded samples. These techniques include the analysis of more fields of view or more grid openings to lower detection limits.

Over loading can be an issue with current OSHA methods that there are analytical techniques available and used by EPA to lower detection limits or avoid overloading. Even if EPA can demonstrate a method that will achieve the desired ECEL and AL limits of detection, there are problems with overloading and media destruction during sampling at higher volumetric flow rates and durations to achieve the desired LOD. In the chlor-alkali industry, under the typical conditions in the cell-renewal areas where the cell is opened using a water spray or, with some of the activities, water pressure spraying, the pressure drop across the filter will become too great to maintain required sampling rates and therefore not viable under these conditions. This is a different condition than the handling of the dry asbestos that occurs in a glove box under negative pressure with bag house collection of dusts. Both conditions can affect the loading of the sample, the pressure drop, the filter integrity and will ultimately bias the results.

Third, it has been known for at least four decades that assessing compliance using a direct comparison of a sample result to the OEL is no better than random chance (Tuggle[42], 1981). The AIHA[5] (2015) presents appropriate statistical guidance regarding appropriate compliance determinants and statistical methods.

The following approach should be considered by EPA to be consistent with AIHA guidance. First, considering that the background concentration of fibers can be highly variable and possibly above the proposed ECEL and AL, a LOD should be selected that allows industrial hygienists to differentiate exposures from background. The lowest practical (from an analytical perspective) ECEL is at least three times background. The typical limit of quantification as it relates to the LOD is 10:3.

---

[4] R.M. TUGGLE (1981) The NIOSH decision scheme, American Industrial Hygiene Association Journal, 42:7, 493-498, DOI: 10.1080/15298668191420134 To link to this article: https://doi.org/10.1080/15298668191420134

[5] Jahn, S., I. Joselito, and B. Bullock: *A Strategy for Assessing and Managing Occupational Exposures*, 4thed. Fairfax, VA: AIHA Press, 2015.

Additionally, EPA should recommend that a compliance metric such as the 95th percentile should not exceed the ECEL or, stated another way, the exceedance fraction should not exceed 5%. Regarding the initial determination, this has already been completed by the three chemical companies with a diaphragm cell chlorine production. The companies have professional industrial hygiene staff and have had staffed industrial hygiene programs for decades. Additionally, the current OSHA Asbestos General Industry Standard has been in place for 28 years. These three companies are already required to comply with the standard. Compliance with an ECEL should be determined using appropriate statistical techniques as defined in AIHA (2015) which means that the decision of acceptability should not be made measurement by measurement, but rather by considering a dataset of six to 10 measurements. Once compliance with the ECEL has been determined in the initial determination step, ongoing sampling should occur on a regular basis, such as quarterly or at least once every six months.

Conclusion and Next Steps

AIHA thanks you for the opportunity to provide feedback on EPA's notice of proposed rulemaking on the manufacturing, processing, distribution, and commercial use of chrysotile asbestos. We look forward to our continued work together, helping protect the health and safety of all workers and their communities. If you have any questions on these comments or other matters, please contact me at mames@aiha.org or (703) 846-0730.

Sincerely,

Mark Ames
Director, Government Relations
AIHA

About AIHA

AIHA is the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety in the workplace and community. Founded in 1939, we support our members with our expertise, networks, comprehensive education programs, and other products and services that help them maintain the highest professional and competency standards. More than half of AIHA's nearly 8,500 members are Certified Industrial Hygienists and many hold other professional designations. AIHA serves as a resource for those employed across the public and private sectors as well as to the communities in which they work. For more information, please visit www.aiha.org.